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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,308	02/09/2001	Luigi Naldini	40511	7081

7590 03/10/2004

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EXAMINER	
FALK, ANNE MARIE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/581,308	Applicant(s) NALDINI ET AL.	
	Examiner Anne-Marie Falk, Ph.D.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed November 26, 2003 has been entered. Claims 1-12 have been cancelled. Claims 13-15 have been newly added.

Accordingly, Claims 13-15 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The request for continued examination filed on January 26, 2004 requests entry of the amendment filed in November 2003. Accordingly, Applicants' submission filed on November 26, 2003 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Nature of the invention and scope of the claims. The claims are directed to a method for treating a host infected with a human immunodeficiency virus (HIV) by exposing the host to an amount

of HIV vector effective to inhibit HIV replication. The claims cover treating any type of HIV infection and inhibiting replication of any HIV. The claims are limited to using an HIV vector that lacks a transgene. Thus, no anti-viral transgene is present on the vector.

Amount of direction or guidance presented and the presence or absence of working examples. Example 2 of the specification describes the inhibition of HIV-1 replication in lymphocytes transduced by HIV-1. The teachings of the specification are limited to *in vitro* assays. No working examples of the claimed invention are described in the specification. The specification also discloses that the invention is believed to function through a competition mechanism whereby vector RNA competes with viral RNA for binding of transactivators and for packaging by the viral particles, thus resulting in inhibition of viral replication.

State of the prior art and predictability of the art. At the time of the invention, successful implementation of viral vector administration for inhibiting HIV replication *in vivo* in a subject was not routinely achievable by those skilled in the art. This is reflected in two reviews published well after the priority date of this application. Romano et al. teaches that, by the year 2000, lentiviral vectors had not been used in clinical trials. The reference further provides reasons detailing why the HIV-1 lentiviral vector system is unlikely to be used in humans for therapy (p. 22, column 2). The art generally teaches that *in vitro* effects were not very often predictive of *in vivo* effects. However, animal model systems for HIV infection are lacking. Miller et al. (2000) teaches that « [a] well-recognized and frustrating hurdle in HIV and AIDS research is the lack of an authentic, reproducible animal model system that recapitulates the entire infectious process of HIV from virus entry and replication to the pathogenic manifestations of the disease and eventual AIDS-like outcome. Several animal models currently in use capture one or a number of events typical of HIV infection, but none encompasses the full spectrum of the disease." (p. 7187, column 1, paragraph 1). The reference provides additional reasons detailing the deficiencies particularly of the macaque-SIV model system.

Accordingly, given the demonstrated lack of predictability in the art, the limited amount of direction given, the state of the prior art with regard to model systems and correlating *in vitro* effects with *in vivo* effects, the quantity of experimentation needed, and the lack of applicable working examples, one of skill in the art would not be able to make and use the claimed invention over the full scope without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is indefinite in its recitation of "wherein the HIV is HIV-1" because "the HIV" has ambiguous antecedent basis as it can refer to th HIV of the host infection or the HIV vector.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 10:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The central official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to William Phillips, whose telephone number is (571) 272-0548.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER